# A study to test whether vicadrostat in combination with empagliflozin helps people with chronic kidney disease

## 1. EU Trial Number and full study title

2024-518457-42-00: A Phase II randomised, double-blind, parallel-group, multicentre, international trial to investigate the safety and efficacy of vicadrostat and empagliflozin administered with simultaneous vs staggered initiation in participants with chronic kidney disease at risk of kidney disease progression

## 2. Rationale

The reason for performing this study is to find out whether a medicine called vicadrostat, used in combination with another medicine called empagliflozin, works in people with chronic kidney disease (CKD). Vicadrostat and empagliflozin are being developed to reduce inflammation and scarring (fibrosis), which are key factors in worsening kidney, heart, and blood vessel health. In previous studies, vicadrostat and empagliflozin have shown potential in slowing down kidney disease progression.

## 3. Objective

The goal of this study is to find out if starting the study medicines, vicadrostat and empagliflozin, at the same time or one after the other helps people with chronic kidney disease. The study aims to compare the effects of starting the study medicines at the same time or one after the other on kidney function, blood pressure, and the amount of potassium in the blood.

## 4. Main study endpoints

The primary endpoint for this study is the change in kidney function, measured by the estimated glomerular filtration rate (eGFR), from the start of the study to Week 14.

## 5. Secondary study endpoints

The following secondary endpoints are planned:

- The change in kidney function, measured by the estimated glomerular filtration rate (eGFR), from the start of the study to Week 12
- The change in blood pressure, measured by systolic blood pressure (SBP), from the start of the study to Week 12
- The change in the amount of protein in the urine, measured by the urine albumin creatinine ratio (UACR), from the start of the study to Week 6
- The change in the amount of potassium in the blood, measured by serum potassium, from the start of the study to Week 12.

## 6. Study design

This is a multi-national, randomised, double-blind, parallel-group clinical study. Participants are in the study for about 4 months.

## 7. Study population

This study is open to adults who are at least 18 years old and have chronic kidney disease (CKD) that is at risk of getting worse. People who have taken a specific type of medication for kidney disease

called SGLT2 inhibitor within 1 month before the start of study treatment or have certain health conditions, such as severe liver disease, cannot take part in this study.

## 8. Interventions

In this study, participants are randomly assigned to one of two groups. In one group, participants take the 2 study medicines, vicadrostat and empagliflozin, at the same time every day for 3 months. In the other group, participants take placebo and empagliflozin for the first 1.5 months, and then they take vicadrostat and empagliflozin together for the next 1.5 months. The study medicines are taken orally as tablets. Placebo tablets look like vicadrostat tablets but do not contain any medicine. The chance of being assigned to either group is the same. The study lasts for about 4 months.

Participants may continue their regular treatment for kidney disease during the study. During study visits, the doctors collect information about participants' health. To assess the study endpoints, participants regularly have blood samples taken.

## 9. Ethical considerations – benefits and risks

Participants may not personally benefit from treatment in this study. But their contribution may provide doctors and researchers with new information about treatment for kidney disease with vicadrostat and empagliflozin. This may benefit other people in the future. Benefits of treatment with vicadrostat and empagliflozin may include potential slowing of the progression of kidney disease.

Any clinical study, treatment and medical test has risks. The study doctor and the study staff monitor participants' safety carefully. In previous clinical studies, vicadrostat and empagliflozin were well tolerated in participants. Risks related to vicadrostat may include health problems related to blood potassium levels, cortisol levels, kidney function, and interaction of medicines. These can usually be treated symptomatically. To minimise the risks, study participants are only exposed to doses that have been safely used in previous studies. Signs of possible injury to the liver will be continuously monitored. For more information, please refer to the Informed Consent Form of this study.

Empagliflozin has been used to treat type 2 diabetes, kidney disease, and heart disease for many years. For more information on the side effects, refer to the European package insert.